## REMARKS

Claims 13-36, 38 and 42-53 remain pending and under examination. The above amendment amends the preamble of each of independent claims 13, 35, 36, and 42 to read "A method of prevention and/or treatment...." rather than "A method of prevention and treatment..," to reflect more accurately the intended scope of the claimed methods. Support for this language can be found in claim 13 as originally filed, as well as in the specification at page 3, line 21; page 4, lines 7-23; and page 8, lines 24-29, which explain that the method can be used either to prevent asthma symptoms (e.g., by administration before the symptoms develop, when the patient expects to encounter an asthma-producing condition) or to treat the symptoms when they occur, and that use to treat active symptoms will have the added benefit of simultaneously reducing the incidence of (i.e., preventing) subsequent asthma attacks, by delivering the anti-inflammatory agent budesonide. No new matter has been added.

Amendment to preambles

Applicant notes that, during an interview with the Examiner on October 18, 2007, Applicant proposed amending the preambles of claims 13, 35, 36, and 42 to substitute "prevention or treatment" for the existing term "prevention and treatment". In the Office action mailed December 4, 2007, the Examiner said that she did not agree to Applicant's proposal because this amendment would broaden the scope of the claims beyond what the Board of Patent Appeals and Interferences had approved in the August 28, 2007, Decision on Appeal remanding the case to the Examiner (the "Board Decision"). Applicant did not pursue the amendment further at that time, but have decided to do so now. Accordingly, the claims are amended herein to say "prevention and/or treatment."

The claims on appeal, which recited "prevention and treatment," had originally been rejected for lack of enablement because the Examiner believed the specification did not enable one of ordinary skill in the art to practice the "prevention" aspect of the claimed method. See, the Board's description of the Examiner's enablement rejection at pages 3-4 of the Board Decision. The Board cited Applicant's arguments that there was ample enabling disclosure to

support the "prevention" aspect, and said "We find that Appellant has the better argument and the rejection is reversed." There is no indication that the Board tied this decision to the fact that the preambles at the time said "prevention and treatment" instead of "prevention and/or treatment." Accordingly, there appears to be no basis for concluding that the Board would have reached a different conclusion had the claims said "prevention and/or treatment." Entry of the present amendment and allowance of the claims as amended is therefore respectfully requested.

Rejection under 35 USC § 101

Claims 13-36, 38, 42 and 43 remain rejected as allegedly being directed to non-statutory subject matter under 35 USC § 101.[1] The Office Action dated June 25, 2009 (the Office Action) at page 7 reasserts the position stated in prior Office actions that, because actual administration of the inhaler to a patient is not an element of the claims, there is "no requirement a practical application actually be associated with [the] providing steps" and "neither a transformation nor reduction would result from the claimed invention because the limitation that the patient actually performs the administration of the claimed composition is not an element of the claim." Thus, the Examiner seems again to be taking the position that a limitation requiring actual administration of the composition is absolutely required in order to qualify as a "transformation" or "reduction" that would satisfy § 101. Applicant previously pointed out that the Examiner had pointed to nothing in the statute nor the case law to support such a position, and that the present claims do effect a "transformation" in that they transform a patient into someone who has an inhaler and recommendations for use of the inhaler. In response, the Office Action says at page 2, "This is not found to be persuasive because the rejection was made based on the Board's remand August 28, 2007 (see page 10 of the remand)." Applicant points out that the Board's instruction to the Examiner "to clearly explain what subject matter the claimed process is transforming or reducing into a different state or thing" is nothing more than a directive to examine and determine the issue, and is not a legal opinion or a decision one way or the other. The Board's instruction on remand certainly does not, in and of itself, constitute a valid basis to

[1] It is noted that the rejection under § 101 has not been applied against claims 44-53.

dismiss Applicant's reasoning as "not found to be persuasive." Rejections must be based on the law, not on instructions by the Board merely to consider an issue. Further, Applicant points out that the present claims are not even the same as the claims considered by the Board on appeal in 2007. The claims under appeal included a single step: instructing a patient. In contrast, the present claims require two steps: (1) providing an inhaler to the patient, and (2) providing a recommendation to the patient regarding use of the inhaler. The Board's remand did not address a claim with those two steps, so could not possibly support the Examiner's conclusory assumption that the present claims do not involve a "transformation."

Further, Applicant points out that "transformation" is not the sole test for patent-eligible subject matter. The Court of Appeals for the Federal Circuit, sitting *en banc*, held in *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008), that claimed subject matter is patent-eligible if it satisfies either of two alternative tests: "**(1) it is tied to a particular machine or apparatus; or (2) it transforms a particular article into a different state or thing.**" Applicants note that the present Office Action as well as all of the prior Office actions since the Board's remand in 2007 have focused on "transformation" as though it is the sole test for patent-eligible subject matter. At no point has the Examiner indicated why she believe that the inhaler device that is recited as an integral part of both steps of the present claims is not "**a particular machine or apparatus**" that satisfies the first *Bilski* test and thus brings the claims comfortably within § 101. Applicant submits that each of the two steps of each of the claimed methods is "tied" to a "particular apparatus," i.e., an inhaler containing a defined composition. Thus, regardless of which *Bilski* test is applied, the present claims constitute patent-eligible subject matter that satisfies the criteria of the statute. Withdrawal of the rejection under § 101 is respectfully requested.

Rejections under 35 USC § 103(a)

Claims 13-15, 17, 18, 20-36, 38, and 42-53 were rejected as obvious over Carling, for the same reasons that have been asserted in multiple prior Office actions. Claims 16 and 19 were rejected as obvious over Carling and further in view of Aberg et al. and Ryrfeldt et al., again for the same reasons as previously asserted. According to the Examiner, Carling's teachings that the

combination of formoterol fumarate dihydrate and budesonide can be used to treat asthma, and that the dosage "strongly depends on the patient (age, weight etc.), severity of disease (mild, moderate, severe asthma etc.)" mean that it would have been obvious to carry out the claimed methods. The Examiner acknowledges at page 9 of the Office Action that the present claims differ from the disclosure in Carling in that the present claims require recommending that a patient use the inhaler "as needed," as determined by the patient. However, the Examiner asserts that such a recommendation would be "obvious," stating that Carling teaches the dosage "strongly depends on the severity of disease (mild, moderate, severe asthma) and the suitable daily dosage is up to 8 inhalation." Applicant has previously pointed out that Carling says the combination should be administered just twice per day (a teaching that the Examiner has acknowledged). Applicant has also previously explained that the teaching in Carling about varying the dosage according to the "severity of disease" means that the physician should set a dosage (always to be administered twice per day) based on the patient's severity of disease, certainly not that the patient is free to do so. The Examiner relies in part on Carling's statement at page 4, lines 3-10: "**This combination has not only a greater efficiency and duration of bronchodilator action but the combination also has a rapid onset of action.**" One should note, however, that the significance of that statement is explained by Carling a few lines later: "**The rapid onset of the long-acting β-agonist gives the patient immediate confirmation that he has taken an adequate dose and thereby avoiding overdosing of both β2-agonist and steroid....The combination according to the present invention permits a twice daily dosing regime as a basic treatment of asthma, including nocturnal asthma.**" (page 4, lines 12-21) Thus, the "rapid onset of action" cited by the Examiner is touted by Carling not as a reason to take the combination whenever the patient feels an asthma attack coming on, but rather as an advantage in the context of a twice-daily dosing regimen, as it gives the patient immediate confirmation that he has taken the presecribed dose and thus reduces the risk the patient will take an extra dose just to be sure. (Though the Examiner appears to believe that Carling teaches that up to 8 doses per day can be "safely inhaled," this passage of Carling shows that those of skill in the art were concerned about the risk of even one extra dose beyond the twice-daily dose set by

the physician.) Applicant has previously explained that those of skill in the art understood that dosages of steroid drugs such as budesonide were never left to the discretion of the patient, as they could potentially produce dangerous side effects, so needed to be carefully monitored by the physician. Applicant provided voluminous evidence to support these assertions, evidence that the Examiner has simply dismissed as "not persuasive" based on nothing more than Carling's general teachings as interpreted by the Examiner. For example, although the Office Action at page 5 acknowledges that the Symbicort® Turbohaler® budesonide/formoterol inhaler product insert[2] warns "**Do not use Symbicort® to relieve an acute attack**" and teaches that the Symbicort® inhaler should be administered twice per day unless the patient's doctor has decided that administration just once per day is sufficient to control the patient's symptoms, the Office Action dismisses this evidence of how one of ordinary skill would have interpreted Carling. The Office Action instead substitutes the Examiner's own reading of Carling that is not supported by any factual evidence of record, and in fact is directly contradicted by multiple lines of evidence provided by Applicant. Applicant submits that Carling would not have rendered any of the claims obvious to one of ordinary skill in the art.

Aberg et al. and Ryrfeldt et al. are cited solely for their alleged respective disclosures of the (R,R) isomer of formoterol (as specified in claim 16) and the 22R epimer of budesonide (as specified in claim 19). Neither reference makes up for the deficiencies of Carling et al. discussed above.

In view of the above, withdrawal of the rejections for obviousness is respectfully requested.

## CONCLUSION

Applicant asks that the rejections of record be withdrawn and the claims allowed. If any questions remain, the Examiner is asked to telephone the undersigned at 808 986 0300 so that they can be resolved.

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[2] See Exhibit A submitted April 3, 2009, with Applicant's Amendment in Reply to Action of October 6, 2008.

A Petition for Extension of Time and an Information Disclosure Statement accompany this Reply. Please apply any charges or credits to deposit account 06-1050, referencing Attorney Docket No. 06275-0188001.

Respectfully submitted,

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